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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/159,068	09/23/1998	ELEFTHERIA MARATOS-FLIER	10276/014002	4696

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/159,068	Applicant(s) MARATOS-FLIER et al.
	Examiner Christine Saoud	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 27, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *47-63* is/are pending in the application.

4a) Of the above, claim(s) *50-60* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *47-49 and 61-63* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *47-63* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I in Paper No. 21 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 50-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 21. Claims 47-49 and 61-63 are under examination in the instant application. Claims 47-49 are being examined only in so far as they read on the elected invention, which is a method of treatment by administration of an antagonist wherein the antagonist is a non-polypeptide drug or chemical.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 47-49 and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are similar to a single means claim in that they require the administration of an MCH antagonist, wherein the antagonist is a non-polypeptide drug or

chemical and wherein the antagonist binds an MCH receptor. MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt* , 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. MCH antagonist), a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. In the instant case, the claims are limited in the sense that polypeptides are excluded from the scope of the claims, but the claims still cover any compound so long as it is not a polypeptide.

The instant specification fails to identify a single non-polypeptide drug or chemical which acts as an antagonist and inhibits eating, appetite or gain of weight. The instant specification discloses that MCH promotes eating behavior, and therefore, this activity appears to be associated with activation of the MCH receptor. However, the instant specification fails to teach or describe even a single non-polypeptide drug or chemical which functions in the manner required for the claimed method. One may argue screening for bioactivity could be done, however, this is basically a "wish to know" and the standard for an enabling disclosure is not one of making and testing. In so far as the instant claims encompass a compounds that have yet to be identified, specific case law bears on this issue: Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 18 U.S.P.Q. 2d, 1016, held that;

> "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. *See Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated."

The fact pattern is directly analogous in that what is claimed are methods of using compounds that have yet to be isolated or characterized for the activity recited in the claims and thereby constitutes a "wish to know" rather than a reduction to practice, absent evidence to the contrary. The decisions of *In re Fisher*, Amgen Inc. v. Chugai, and *In re Wands* have been relied upon by the court in a recent CAFC decision, Genentech, Inc. V. Novo Nordisk, 42 USPQ2d, 100 (CAFC 1997) because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of the claims must be based upon the predictability of the claimed subject matter and no on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to

work than not without actually making and testing them, then the instant application does not enable instant the claims.

5. Claims 47-49 and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a method of inhibiting appetite or the gain of weight by administration of an MCH antagonist, wherein the antagonist binds an MCH receptor and wherein the antagonist is a non-polypeptide drug or chemical. The instant specification fails to describe even a single non-polypeptide drug or chemical which meet the limitations of the claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant does not have possession of any non-polypeptide drug or chemical which binds to the MCH receptor and is an antagonist of MCH. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The subject matter of the claims is as described above. The specification teaches peptide analogs based on MCH which may or may not function as antagonists of MCH. First, the claims provide no structure for the compounds which are encompassed in the claimed method, except that the compounds are not polypeptides. The

specification fails to describe any compounds encompassed by the claims and those examples in the specification are not predictive of what is claimed since they are peptide analogs which are specifically excluded from the claims (see restriction election). The breadth of the claims is such that the claims encompass any non-polypeptide drug or chemical yet to be discovered. There is a lack of guidance or teaching regarding structure and function of the compounds (drug or chemical) because there are no examples provided in the specification, the peptide analogs in the specification are not predictive of non-polypeptide drugs and chemicals and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims because there are no drugs or chemicals disclosed which function in the manner required by the claims. The specification does not provide a complete structure of any drug or chemical which would have the necessary activity to function in the claimed method. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of

species for the claimed genus because the specification fails to teach even a single drug or chemical which is a non-polypeptide compound. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed drug and/or chemical molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method screening for these compounds. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) The instant claims

are directed to drugs and/or chemicals, which could be identified by screening, but for which, there is no written description. As in Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class because the specification provided only the bovine sequence. In the instant situation, the specification fails to provide even a single example of the drugs and/or chemicals required by the claims, regardless of whether they could be made, isolated or identified by methods of screening.

Response to Arguments

6. Applicant's arguments filed 29 April 2002 have been fully considered but they are not persuasive. Applicant's arguments will be addressed only in so far as the relate to the elected invention, which is a method of treatment by administration of an MCH antagonist, wherein the antagonist is a non-polypeptide drug or chemical. Applicant asserts that the Declaration of Dr. Maratos-Flier provides evidence that one of ordinary skill in the art could perform the claimed methods using the knowledge in the art and the guidance provided in the specification. However, the Declaration under 37 CFR 1.132 filed 29 April 2002 is insufficient to overcome the rejection of claims 47-49 and 61-63 based upon lack of enablement and lack of written description as set forth above for the following reasons.

Applicant asserts that the methods in the specification "have been able to identify MCH antagonists that bind competitively to the MCH receptor and perform the claimed methods" (see response at page 5). However, a method of screening is not a written description of those compounds which are required for the claimed method. As pointed out above, the skilled artisan

cannot envision the detailed chemical structure of the encompassed drug and/or chemical molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method screening for these compounds. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. The Declaration relies solely upon use of an assay for identification of non-peptide antagonists to be used in the claimed method (specifically at paragraph #9, page 4), but as stated above, a method of identification of a compound is not a written description of what is being claimed. Furthermore, the evidence of Takekawa et al. is not prior art and cannot be used to show what was known at the time of the instant invention. In terms of enablement of the claimed invention, without any starting point (i.e. any structure of even a single non-peptide drug or chemical), it would require undue experimentation to determine which non-peptide drugs/chemicals would work in the method which is claimed. As pointed out above, what is claimed are methods of using compounds that have yet to be isolated or characterized for the activity recited in the claims and thereby constitutes a "wish to know" rather than a reduction to practice, absent evidence to the contrary. the amount of experimentation required to practice the claimed method would be undue because there is not a single example, there is no guidance as to which molecules would work, the quantity of experimentation is enormous due to the screening of all classes of drugs and chemicals to determine which would act in the manner required by the claims, there is no predictability since there is no structure to go on

for selection of which classes of drugs/chemicals which may possibly function, and there is no guidance in the prior art. Therefore, the instant claims lack enablement and written description for the claimed invention, absent evidence to the contrary.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud